

IN THE DISTRICT COURT OF THE UNITED STATES
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
ASHEVILLE DIVISION

CIVIL NO. 1:05CV346

SCITECK CLINICAL LABORATORIES,)	
INC., a Delaware corporation,)	
)	
Plaintiff,)	
)	
Vs.)	<u>MEMORANDUM AND</u>
)	<u>ORDER OF DISMISSAL</u>
)	
UNITED STATES DEPARTMENT OF)	
HEALTH AND HUMAN SERVICES,)	
An Agency of the United States)	
Government,)	
)	
Defendant.)	
)	

THIS MATTER came on for hearing before the Court on November 29, 2005, on Plaintiff's motion for a preliminary injunction. The parties were represented by counsel and oral arguments were heard. Having considered the submissions of the parties, arguments of counsel, and the applicable legal standards, the Court denies Plaintiff's motion for preliminary injunction and vacates the temporary restraining order entered November 21, 2005.

I. FACTS

Plaintiff is a drug testing laboratory located in Western North Carolina.

In 2003, Plaintiff obtained certification as a Substance Abuse and Mental Health Services Administration (SAMHSA) certified laboratory. **Complaint, ¶**

6. SAMHSA certification falls within the purview of Defendant. *Id.*

Continued certification as a SAMHSA certified laboratory is administered through the National Laboratory Certification Program (NLCP), who in turn contracts with Research Triangle Institute (RTI) to conduct inspections and evaluations of SAMHSA certified laboratories in North Carolina. *Id.*, ¶ 7.

Plaintiff's SAMHSA certification was suspended on November 14, 2005, with permanent revocation 30 days thereafter. **See, Exhibit B, Letter dated November 14, 2005, to John Lizzaraga from Robert Stephenson II, attached to Complaint**). Plaintiff filed a verified complaint in this Court on November 21, 2005, seeking a temporary restraining order (TRO) and preliminary injunction to prevent loss of its certification, declaratory relief, and asserting claims for Equal Protection and Due Process violations. On the record before it at the time, this Court granted Plaintiff's motion for a TRO,

and set Plaintiff's motion for preliminary injunction for hearing on November 29, 2005. **See Temporary Restraining Order, filed November 21, 2005.**

II. STANDARD

"Granting a preliminary injunction requires that a district court, acting on an incomplete record, order a party to act, or refrain from acting, in a certain way. The danger of a mistake in this setting is substantial." **Scotts Co. v. United Indus. Corp.**, 315 F.3d 264, 284 (4th Cir. 2002) (quotations omitted). As such, a preliminary injunction is considered "an extraordinary remedy involving the exercise of a very far-reaching power, which is to be applied 'only in [the] limited circumstances' which clearly demand it." **Direx Israel, Ltd. v. Breakthrough Med. Corp.**, 952 F.2d 802, 811 (4th Cir. 1991) (quoting **Instant Air Freight Co. v. C.F. Air Freight, Inc.**, 882 F.2d 797, 800 (3d Cir. 1989)). For that reason, "[w]henever the extraordinary writ of injunction is granted, it should be tailored to restrain no more than what is reasonably required to accomplish its ends. Particularly is this so when preliminary relief, on something less than a full record and full resolution of

the facts, is granted.” ***Consolidation Coal Co. v. Disabled Miners of Southern W. Va.*, 442 F.2d 1261, 1267 (4th Cir. 1971).**

The standard in this Circuit for entry of a preliminary injunction is the “hardship balancing test.” ***Direx Israel, Ltd., supra; see also Wetzel v. Edwards*, 635 F.2d 283, 287 (4th Cir. 1980).** Under the “hardship balancing test,” the Court must consider four factors in deciding whether to grant or deny interim injunctive relief: “(a) plaintiff’s likelihood of success in the underlying dispute between the parties; (b) whether plaintiff will suffer irreparable injury if interim relief is denied; (c) the injury to defendant if an injunction is issued; and (d) the public interest.”¹ ***Wetzel, 635 F.2d at 287 (footnote added).*** Of these four factors, the two most important are “probable irreparable injury to the plaintiff if an injunction is not issued and likely harm to the defendant if an injunction is issued.” ***Id.***

When deciding whether to grant a preliminary injunction, the court must first determine whether the plaintiff has made a strong showing of irreparable harm if the injunction is denied; if such a showing is made, the court must then balance the likelihood of harm to the plaintiff against the likelihood of harm to the defendant. If the balance of the hardships tips decidedly in favor

¹The Court is also guided by the mandates of the Federal Rules of Civil Procedure, which govern the procedural requirements attendant to the granting of injunctive relief. **See, Fed. R. Civ. P. 65.**

of the plaintiff, then typically it will be enough that the plaintiff has raised questions going to the merits so serious, substantial, difficult, and doubtful, as to make them fair ground for litigation and thus for more deliberate investigation. But if the balance of hardships is substantially equal as between the plaintiff and defendant, then the probability of success begins to assume real significance, and interim relief is more likely to require a clear showing of a likelihood of success.

Scotts Co., supra, at 271 (quotations and internal citations omitted); see also Doe v. Wachovia Corp., 268 F.Supp.2d 627, 630-31 (W.D.N.C. 2003).

When considering the harm to the parties flowing from the issuance or non-issuance of the requested preliminary injunction, the real issue for the Court's consideration is the level of harm resulting from the *improper* grant or denial of the petitioner's request. **See Scotts Co., supra, at 284.**

If the judge grants the preliminary injunction to a plaintiff who it later turns out is not entitled to any judicial relief – whose legal rights have not been violated – the judge commits a mistake whose gravity is measured by the irreparable harm, if any, that the injunction causes to the defendant while it is in effect. If the judge denies the preliminary injunction to a plaintiff who it later turns out is entitled to judicial relief, the judge commits a mistake whose gravity is measured by the irreparable harm, if any, that the denial of the preliminary injunction does to the plaintiff.

Id., at 284-85 (quoting American Hosp. Supply Corp. v. Hosp. Prods. Ltd., 780 F.2d 589, 593 (7th Cir. 1986)). Finally, a petitioner must always show some risk of probable irreparable injury, as likelihood of success on the merits

alone, without any showing of a risk of irreparable harm, is not sufficient to warrant the issuance of a preliminary injunction. *See, Blackwelder Furniture Co. v. Seilig Mfg. Co., Inc.*, 550 F.2d 189, 196 (4th Cir. 1977).

III. ANALYSIS

A. Irreparable harm to Plaintiff

The first step is for Plaintiff, as the party requesting preliminary injunctive relief, to “make a ‘clear showing’ that [it] will suffer irreparable harm if the court denies [its] request.” *Multi-Channel TV Cable Co. v. Charlottesville Quality Cable Operating Co.*, 22 F.3d 546, 551 (4th Cir. 1994). Jack Smith, Plaintiff’s President and Chief Operating Officer, has averred that if Plaintiff loses its SAMHSA certification, it will suffer the following damages:²

- a. Six employees will have to be immediately released from their jobs and many are the sole providers for their families.
- b. Income of close to \$100,000 per month will be lost.

²The irreparable harm listed by Mr. Smith at ¶ 11d – that clients in Western North Carolina will incur additional time and expense in having to use a laboratory outside the area – is harm flowing to the community or public at large, rather than irreparable harm flowing to Plaintiff, and is, therefore, not considered by the Court at this particular juncture.

- c. Hundreds of clients using Sciteck for drug testing, both federal clients and private sector clients, who require SAMHSA certification will be lost.
 - ...
- e. Sciteck will not be able to competitively compete for drug testing in the market again since the clients lost will not return.
- f. The overall loss in investment and income will be in the millions of dollars.

Affidavit of Jack Smith, attached to Plaintiff's Motion for Temporary

Restraining Order, filed November 21, 2005, ¶ 11.

“[W]hen the record indicates that [plaintiff's loss] is a matter of simple mathematical calculation, a plaintiff fails to establish irreparable injury for preliminary injunction purposes.” ***Multi-Channel TV Cable Co., 22 F.3d at 551-52 (quotations omitted).*** Therefore, were Plaintiff's asserted irreparable injury merely the loss of income or the loss in investment and income as set forth in Smith's Affidavit, Plaintiff would be unable to satisfy its burden and a preliminary injunction would be inappropriate. However, Plaintiff's irreparable harms go beyond mere monetary damages. Loss of its SAMHSA certification, according to Plaintiff, will result in permanent loss of both government and private sector clients, and in Plaintiff being unable to competitively compete in the marketplace. There is no way to quantify these immediate, irreparable harms, and “when the failure to grant preliminary relief creates the possibility

of permanent loss of customers to a competitor or the loss of goodwill, the irreparable injury prong is satisfied.” *Id.*, at 552 (citing *Merrill-Lynch, Pearce, Fenner and Smith v. Bradley*, 756 F.2d 1048, 1055 (4th Cir. 1985)).

Therefore, the Court finds that Plaintiff has satisfied its initial burden of making a clear showing that the improper denial of Plaintiff’s motion for a preliminary injunction will result in immediate irreparable harm. *Id.*, at 551.

B. Harm to Defendant

The Court must now assess the harm that will flow to Defendant if the preliminary injunction is improperly granted, and balance that harm against the possible irreparable injury to Plaintiff. *Id.*, at 552. Defendant is concerned with ensuring that drug testing labs given its imprimatur as “SAMHSA certified” are operated at or above a minimal threshold level of competence and proficiency as established by the mandatory guidelines. **68 Fed. Reg. 19666 at § 3.2.** Defendant’s interest, therefore, is in accurate testing in order to protect the safety and rights of employers, employees, the government, and the public at large. *Id.*, at § 3.2(b) (“**The ability to accurately determine the presence or absence of specific drugs/metabolites**

or to accurately determine the validity of a urine specimen is critical to achieving the goals of the testing program and to protect the rights of the Federal employees being tested.”).

Defendant’s interest is substantial, as is the harm that Defendant could suffer if this Court were to improperly grant Plaintiff’s motion for a preliminary injunction. Defendant has questioned, over a significant period of time, the manner in which Plaintiff Sciteck was being operated and the validity of the test results promulgated by the laboratory. **See, Exhibit 2, November 14, 2005, Suspension Letter, included in Defendant’s Exhibits to Response for a Preliminary Injunction, filed November 28, 2005, at 1 (“The deficiencies identified prevent Sciteck Clinical Laboratories from ensuring the reliability and accuracy of its drug testing and reporting. The deficiencies are material and the suspension of certification is required to protect the interests of the United States and its employees and to protect the public health and safety.”); Exhibit 4, Affidavit of Ernest W. Street, included in Supplemental Exhibits to Defendant’s Response, filed November 29, 2005, ¶ 4 (“The number and range of errors observed in PT cycles 8, 9 and 10 bring into question the accuracy of any given report emanating from this laboratory. . . .**

. I have never observed the number and type of errors demonstrated by Sciteck Laboratories."); Exhibit 6, Affidavit of Michael R. Baylor, *included in Supplemental Exhibits to Defendant's Response, ¶ 8* ("[I]n the tenth Performance Testing cycle, Sciteck failed to test properly three samples. One sample Sciteck failed to detect and report as invalid and two samples Sciteck failed to detect and report as adulterated. Sciteck's failure to properly test these samples resulted in false negative reports for these test samples."); *see generally, Exhibit A, attached to Plaintiff's Complaint (containing the documented deficiencies from each of Plaintiff's evaluations).* Allowing Plaintiff to continue operating under an erroneously issued preliminary injunction irreparably harms Defendant in that the safety and rights of employers, employees, and the public at large could be compromised by unreliable tests performed by a laboratory in non-compliance with the minimal standards of operation, which laboratory would have been unable to continue performing SAMHSA certified testing but for this Court's erroneously issued preliminary injunction. As Defendant stated in its response to Plaintiff's motion:

Under the present state of affairs, the Plaintiff's drug testing and reporting are not reliable. Consequently, the unreliability of the

Plaintiff's drug testing and reporting puts at risk the federal employees and agencies who must rely on such tests to ensure drug free workplaces. . . . To grant a preliminary injunction would create the potential of irreparable harm because it would permit the plaintiff's unreliable drug testing and reporting to continue, with potential impact upon the public at large.

Defendant's Response, at 6.

Having balanced the harm attending the parties from this Court's improperly granting or denying Plaintiff's motion for a preliminary injunction, the Court does not find that the potential harm to Plaintiff clearly outweighs the potential harm to Defendant. Rather, the Court finds that the balance of hardships is substantially equal as between the Plaintiff and Defendant. Therefore, "the probability of success begins to assume real significance," and Plaintiff must make a clearer showing of a likelihood of success on the merits in order to obtain preliminary injunctive relief. *Scotts Co., supra, at 271.*

C. Likelihood of Success on the Merits

The thrust of Plaintiff's complaint is that it is in compliance with the minimal standards for a SAMHSA certified laboratory, that it is being treated differently than other SAMHSA certified laboratories, and that its certification is being suspended and revoked not because of any shortcomings in the

laboratory but rather because Defendant, by and through its agent RTI, is attempting to run Plaintiff out of business. **See generally, Complaint.** Plaintiff, therefore, claims Equal Protection and Due Process violations under the Fifth and Fourteenth Amendments to the United States Constitution, and also seeks “a judicial declaration striking the suspension and/or proposed revocation of Plaintiff’s SAMHSA certification and further directing that the issue of such certification be revisited by the Defendant through supervision and direction of this Court under guidelines to insure an objective inspection directed towards such certification.” *Id.*, ¶¶ 28, 29-32. The forecast of evidence at this point, however, does not support Plaintiff’s position.

The mandatory guidelines establish the minimum standards for a laboratory to attain and sustain SAMHSA certification. “A laboratory must meet all the pertinent provisions of these Guidelines in order to qualify for and maintain certification under these standards.” **69 Fed. Reg. 19667 at § 3.3.** The Secretary of the Department of Health and Human Services has the right to suspend or revoke a laboratory’s certification “if the Secretary determines that revocation is necessary to ensure the full reliability and accuracy of drug and validity tests and the accurate reporting of tests.” *Id.*, at § 3.13(a). The

evidence before the Court lends itself substantially more to a conclusion that Defendant was acting within its rights under the mandatory guidelines “to ensure the full reliability and accuracy of drug and validity tests and the accurate reporting of tests,” than it does to a conclusion that Plaintiff’s certification was suspended as a result of disparate, unfair treatment flowing from some sort of vendetta or ill-will. *Id.*; *see also*, Complaint, ¶¶ 13-18, 21, 28, 29-32.

The records of Plaintiff’s evaluations and performance testing reveal numerous concerns dating back as far as June 2003. There have been problems with, among other things, security³, chain of custody⁴, method validation/periodic re-verification⁵, and quality assurance.⁶ Perhaps most

³See Document Review and Critique, Date: 26 June 2003, at Section F. Security; Document Review and Critique, Date: 11 December 2003, at Section F. Security; Document Review and Critique, Date: 17 June 2004, at Section D. Chain of Custody; Letter dated May 19, 2005, to John Lizzaraga from Craig Sutheimer (noting security issues during the April 2005 special inspection), *all included in Exhibit A, attached to Complaint*; Exhibit C, Document Review and Critique, Date: 25 August 2005, at Section F, *attached to Complaint*.

⁴See Document Review and Critique, Date: 11 December 2003, at Section D. Chain-Of-Custody, *included in Exhibit A, attached to Complaint*.

⁵See Document Review and Critique, Date: 11 December 2003, at Section S. Method Validation/Periodic Re-Verification; Letter dated May 19, 2005, to John Lizzaraga from Craig Sutheimer (noting

troubling was Plaintiff's testing accuracy problems during the tenth Performance Testing cycle.⁷ In fact, Plaintiff was informed as early as January 2005 that it was in danger of losing its SAMHSA certification. **See Letter dated January 10, 2005, to John Lizzaraga from Deborah Denson, included in Exhibit A, attached to Complaint; see also Letter dated May 19, 2005, to John Lizzaraga from Craig Sutheimer, included in Exhibit A, attached to Complaint.**

In addition to these problems, Plaintiff has failed to maintain a fully acceptable Responsible Person (RP) as required by the mandatory guidelines. Plaintiff alleges that its conditional RP, John Lizzaraga, has been treated

methodvalidation/periodic re-verification issues noticed during the April 2005 special inspection), *all included in Exhibit A attached to Complaint.*

⁶See Document Review and Critique, Date: 17 June 2004, at Section G. Quality Control Materials and Reagents, and Section H. Quality Assurance: Review of QC Results; Letter dated May 19, 2005, to John Lizzaraga from Craig Sutheimer (noting quality control and quality assurance problems noticed during the April 2005 special inspection), *all included in Exhibit A, attached to Complaint; Exhibit C, Document Review and Critique, Date: 25 August 2005, at Section G. Quality Control Materials and Reagents, and Section H. Quality Assurance: Review of QC Results, attached to Complaint.*

⁷See Baylor Affidavit, ¶ 8 (noting Plaintiff's failure to properly test three samples, which resulted in false negative reports).

unfairly by Defendant, and that this unfair treatment is a substantial root cause of the dispute in this case. **See, e.g., Complaint, ¶ 18; Brief in Support of Plaintiff's Motion for Temporary Restraining Order.** However, the evidence shows the following:

Plaintiff proposed Mr. Lizzaraga as the RP in April 2004. **See Letter dated April 2, 2004, to Susan Crumpton from Edwin Armitage, included in Exhibit A.** Defendant found Mr. Lizzaraga conditionally acceptable in April 2004, and Plaintiff was informed what deficiency was found in Mr. Lizzaraga as well as what needed to be done in order to correct this specific deficiency. **See Letter dated April 14, 2004, to Dr. Edwin Armitage from Michael Baylor, included in Exhibit A.** Mr. Lizzaraga was also made aware that his “knowledge in all areas of RP responsibilities [would] be assessed during the next regularly scheduled inspection,” and that “[i]n order to continue to function as the RP of the laboratory, [he] must be found fully acceptable as RP during that inspection.” **See Letter, dated April 28, 2004, to John Lizarraga from Michael Baylor, included in Exhibit A.** Further deficiencies were noted during the next inspection. Defendant continued to designate Mr. Lizzaraga as conditionally acceptable, outlined the deficiencies, and informed

Mr. Lizzaraga that he needed to be found fully acceptable at the next inspection or the lab would not be able to continue to operate (at least without a different, acceptable, RP). **See Letter dated June 25, 2004, to John Lizzaraga from Michael Baylor, *included in Exhibit A*.** Mr. Lizzaraga was not found fully acceptable at the next inspection, and a special inspection was scheduled specifically to evaluate Mr. Lizzaraga's performance for a third time. **See Letter dated January 10, 2005, to John Lizzaraga from Michael Baylor, *included in Exhibit A*.** Mr. Lizzaraga's performance was found unacceptable during the special inspection, and Plaintiff was informed that its certification would be suspended and/or revoked following the next regular inspection if Plaintiff did not have a fully acceptable RP. **See Letter dated May 19, 2005, to John Lizzaraga from Craig Sutheimer, *supra*.** Neither Mr. Lizzaraga nor the newly proposed RP, Dr. Gregory A. Hobbs, were found fully acceptable at the August 25-26, 2005, inspection. **See Letter dated September 27, 2005, to John Lizzaraga from Craig Sutheimer, *included in Exhibit A*.**

In summary, the evidence appears to be that Mr. Lizzaraga was allowed to operate as Plaintiff's RP for more than a year without ever being found fully acceptable. After each evaluation he was informed of his deficiencies, and

while those particular problems may have been corrected, additional problems arose at subsequent evaluations. Nevertheless, Defendant provided Mr. Lizzaraga with numerous opportunities to qualify as the Responsible Person. Although certainly not conclusive, it would appear to this Court that if Defendant were truly refusing to certify Mr. Lizzaraga in some unfair way, or as the result of some personal dislike or vendetta, Defendant would not have given Mr. Lizzaraga and Plaintiff opportunity after opportunity for more than a year to improve his and its performance.⁸ Rather, Defendant would have forced Plaintiff to choose a new RP or suspended Plaintiff's certification long before November 2005.

Based on the above-summarized evidence, as well as all of the remaining evidence submitted by the parties but not herein cited by the Court, the Court finds that Plaintiff has failed to make a sufficient showing of a clear likelihood of success on the merits.

⁸Additionally, Plaintiff was given the opportunity to have an independent party observe the special inspection, and was also given the opportunity to challenge "for cause," on a conflict of interest basis, the special inspectors who evaluated Plaintiff's laboratory during the April 4 and 5, 2005, special inspection. **See Letter dated February 18, 2005, to Jack Smith from Donna Bush, included in Exhibit A.**

D. Public Interest

The public interest in this case is twofold. First, as noted by the Plaintiff, if the Court denies Plaintiff's motion for a preliminary injunction, the segment of the public that utilizes Plaintiff's drug testing services and requires testing by a SAMHSA certified laboratory will have to transfer its business to a laboratory outside Western North Carolina. **Smith Affidavit, *supra*, ¶ 11d.**

This transference will come with additional time and costs to these clients.

Id.

However, the interest of the public at large – including Plaintiff's clients – includes having reliable drug testing conducted by a competent laboratory operating at, at the very least, a minimal level of proficiency under the guidelines and regulations. Additionally, employers and employees have an interest in ensuring that samples are accurately tested and reported, so that employers are not employing drug users falsely reported as clean, and clean employees are not subjected to false positive results. As Defendant stated, “the public interest will be protected and advanced by the suspension [of Plaintiff's SAMHSA certification and the denial of Plaintiff's motion for preliminary injunctive relief] because the samples collected in Western North

Carolina will be express shipped to certified labs which have not been found to be deficient in their testing and reporting, thus ensuring the reliability and accuracy that the Defendant has found is lacking in the Plaintiff.”

Defendant's Response, at 8-9.

Considering these conflicting interests, it is clear to this Court that the more important interest is that of public safety, and reliable and accurate testing. The “public interest” factor, therefore, weighs in favor of denying Plaintiff’s motion for a preliminary injunction.

Lastly, the mandatory guidelines found in the Federal Register require that “[b]efore any legal action is filed in court challenging the suspension or proposed revocation [of SAMHSA certification], respondent shall exhaust administrative remedies provided under this subpart, unless otherwise provided by Federal Law.” **69 Fed. Reg. 19673 at § 4.15.** Based on the pleadings and allegations before the Court at the time Plaintiff’s motion for a temporary restraining order was granted, the Court permitted Plaintiff to bypass this requirement on the grounds that the Defendant’s agent RTI was alleged to be determined to revoke Plaintiff’s certification regardless of the way Plaintiff’s lab was operating, and that the result of the administrative appeal

provided in the Regulations would, therefore, be an unwarranted foregone conclusion. **See Plaintiff's Brief in Support of Motion for Temporary Restraining Order, at 2-3; *NationsBank Corp. v. Herman*, 174 F.3d 424, 430 (4th Cir. 1999).** With a more complete record before the Court at this stage, the result of the administrative appeal does not appear to be a foregone conclusion in the manner argued by Plaintiff. The Court finds that Plaintiff has, therefore, failed to meet its burden of providing sufficient grounds for waiving the exhaustion of administrative remedies requirement, and this matter, therefore, will not be justiciable unless and until Plaintiff proceeds through the appeals process provided by the mandatory guidelines. **See *NationsBank Corp.*, 174 F.3d at 428** ("Where Congress has intended to require administrative exhaustion prior to any judicial challenges to an agency's enforcement of a law or regulation, courts enforce that requirement unless a party provides grounds for waiving it in a particular case."); 69 Fed. Reg. 19670-73 (Subpart D - Procedures for Review of Suspension or Proposed Revocation of a Certified Laboratory).

IV. ORDER

IT IS, THEREFORE, ORDERED that Plaintiff's motion for a preliminary injunction is **DENIED**.

IT IS FURTHER ORDERED that the temporary restraining order issued by the Court on November, 21, 2005, is **VACATED**, and this matter is hereby **DISMISSED WITHOUT PREJUDICE**.

Signed: December 1, 2005



Lacy H. Thornburg
United States District Judge

